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Fitness for Kids - Effects of a physical activity preschool-based cluster-randomized intervention

Submission date	Recruitment status	[ ] Prospectively registered
10/10/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/10/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Children worldwide are increasingly inactive and show risk factors linked to cardiovascular diseases, which may lead to the early-onset of such conditions. High blood pressure is one of the main risk factors associated with cardiovascular disease. Although the absolute risk of developing cardiovascular diseases in childhood is very low, children exhibiting cardiovascular risk factors are at increased risk for cardiovascular events later in life. It is therefore of urgent importance to prevent the development of risk factors and diseases in children by implementing early interventions. A number of school-based activity interventions exist, but only a few have been performed in preschool settings. Moreover, previous studies have demonstrated that socioeconomic disadvantages negatively affect lifestyle-related behavioral patterns in children. Therefore, the aim of the study is to assess the effectiveness of an exercise program on several health-related outcomes in preschoolers, with focus on socioeconomic background.

Who can participate?
Children aged 3 to 6

What does the study involve?
Participants are allocated to one of two groups. Those in the first group undergo a physical activity program using everyday materials. Those in the second group follow up on their daily routine und do not receive additional exercises. Before and after six months of exercise intervention, children of both groups are measured their blood pressure, pulse wave velocity and anthropometric data. Furthermore, all children perform a motor skill test that examine their flexibilty, speed, strength and coordination. Parents are asked to fulfill a questionnaire on children's physical activity level, family diseases, education and lifestyle behavior.

What are the possible benefits and risks of participating?
All participants receive additional exercise sessions. Preschools who are randomized to the control group have an opportunity to receive the exercise program once the study is completed if they wish to do so. Information obtained from this study may benefit preschool exercise environment in the future. By taking part in this study there are no risks of physical injury or

harm. There are no direct risks however participant’s may experience discomfort when measuring hemodynamic parameters.

Where is the study run from?
This study is being run by University Medical Center Hamburg-Eppendorf (Germany) and takes place in different preschools in Hamburg (Germany).

When is the study starting and how long is it expected to run for?
March 2015 to July 2017

Who is funding the study?
University Medical Center Hamburg-Eppendorf, Kaufmännische Krankenkasse (Germany)

Who is the main contact?
Dr. Claudia Hacke
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PV5019

Study information

Scientific Title
Fitness for Kids - a cluster-randomized controlled physical activity intervention study to improve the cardiovascular risk and motor performance in preschoolers

Study objectives
The purpose of this study is to determine the effect of a six months preschool-based physical activity intervention on blood pressure, arterial stiffness, anthropometrics, physical activity and motor skill performance in 3-6 year old children.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Association of Hamburg (Weidestraße 122b, D-22083 Hamburg), 15/06/2015, ref: ID: PV5019

Primary study design
Interventional

Study design
Randomised parallel assignment open label prevention single-centre study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Blood pressure and arterial stiffness

Interventions
After recruitment and selection of child care centers, meetings are held to clarify the purpose and randomization process of the trial to the centers' administrators and teachers. Based on the number of potentially participating groups in each center, parents or legal guardians are informed by a letter explaining the aim and procedure of the study. The randomisation process is conducted by the principal investigator using a computer-generated random number table, stratified for two social areas of high and low migrations rates, in the presence of other noninvolved researchers. All groups within a center are assigned to the group given by the child care center randomization. The institutions are randomized to take part as either intervention or control centers. Controls are asked to follow up on their daily routine, and those centers are offered the intervention after final data collection. Baseline measures are carried out after the randomization with preschools aware of the randomization results. This is also known to the staff that conduct the tests and administer the intervention.

The two study arms are:
Experimental: Physical activity intervention (60 minutes of physical activity on 2 weekdays).
Comparator/Control: This includes the usual practice.

The program consists of a child-friendly and joyful intervention using cost-effective everyday materials. A video description of the exercise program can be accessed on the project website: www.fitnessfuerkids.de. Child care centers give their oral agreement to provide 60 minutes on two weekdays over a period of six months. The exercise program do not target specific intensity levels, but integrates whole-body movement games resulting in both lower and higher intensities. Furthermore, movements are embedded into narrated stories, music and obstacle-courses. Psychomotor forms of play and dances are also elements of the program as well as functional gymnastics. Everyday materials, e. g. sponges, swatters, yoghurt cups, newspaper or clothespins, are used in each lesson and promote the creativeness of the children. Emphasis is given to change the physical environment by collecting material during the intervention period in order to ensure the ongoing implementation of the programs' key elements. Every lesson is guided by a thematic focus, e. g. 'hoops' or 'spring', and starts with a warm-up including a welcome ritual, followed by a main part and finished with relaxation exercises. Elements are regularly replicated and, in principle, adapted to the children's ability and physical conditions. Lessons are diversified to keep the joy and motivation high. A minimum of one teacher from

each group attends every lesson in order to incorporate elements of the exercise program into daily routine after the end of the study. During the intervention period teachers are encouraged to replicate parts of the program in one additional lesson on one of the remaining weekdays. The exercise sessions are provided by hands-on experienced sports students of the University of Hamburg with expertise in teaching and supervising children and adolescents. Before the start of the intervention, instructors participate in a 4-hour workshop carried out by the initiators of the activity program and are provided with information material and a manual including ideas and examples for exercise lessons. Teachers also receive a manual including a collection of games and exercises to plan and organize daily physical activity lessons. Moreover, instructors and teachers are provided with CD's of children's music to serve as motivation and to facilitate a childlike and entertaining physical education. Instructors monitor the number of executed exercise lessons per week as a fidelity assessment. At the end of the intervention, teachers finish with an exam by conducting one activity lesson and receive a certificate for a successful participation. No other non-exercise or home program components are performed during the study.

Intervention Type
Behavioural

Primary outcome(s)
Peripheral systolic and diastolic blood pressure is measured using the oscillometric device at baseline and 6 months.

Key secondary outcome(s)
1. Central systolic and diastolic blood pressure is measured using the oscillometric Mobil-O-Graph device at baseline and 6 months…
2. Pulse wave velocity is measured using the oscillometric Mobil-O-Graph device at baseline and 6 months
3. Anthropometric measures (height, weight, waist circumference) is measured using measurements at baseline
standard anthropometric methods with the use of portable scales and stadiometers (Seca799, Medical Line Hamburg, Germany) at baseline and 6 months
4. Physical Activity is measured as the weekly activity during leisure time and in organized sports, moderate-to-vigoruous physical activity using a questionnaire to the parents at baseline and 6 months
5. Motor skill performance is measured using the motor skill test at baseline and 6 months
6. Education, family diseases, physical activity, lifestyle are measured using a questionnaire to parents/legal guardians at baseline and 6 months (except for parental educational level, this was only measured at baseline)

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. 3-to-6-year old children visiting a preschool in the city of Hamburg on regular basis
2. No other physical activity program exist in participating preschools

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
All

Key exclusion criteria
Health conditions that do not allow unrestricted physical activity engagement or evaluation.

Date of first enrolment
15/06/2015

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center Hamburg-Eppendorf
Hamburg
Germany
20246

Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center Hamburg-Eppendorf, Kaufmännische Krankenkasse

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Claudia Hacke from c.hacke@uke.de

IPD sharing plan summary
Available on request